杭州东瑞医药科技有限公司 HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Lincomycin Hydrochloride

Batch No.: 110200920	Quantity: 1114.61kg
Date Of Report: 2011.03.12	Specification: EP7.0
Manufacture Date: 2011.02.28	Expiry Date: 2014.01

TESTS:

Items	Specification	Results
Characters	White or almost white crystalline powder	Conforms
Identification	IR:consistent with that obtained with lincomycin hydrochloride reference standard	Conforms
	The solution gives reaction(a) of chlorides	Conforms
Specific optical rotation	+135°~+150°	+141°
Appearance of solution	Clear and not more intensely coloured than reference solution Y6	Conforms
РН	3.5~5.5	4.5
Lincomycin B	≤5.0%	2.3%
Water	3.1%~4.6%	4.3%
Sulphated ash	≤0.5%	0.1%
Bacterial endotoxins	<0.50 IU/mg	<0.50 IU/mg
Heavy metals	≤5ppm	<5ppm
Residual solvents	1-Butanol: ≤5000ppm	116ppm
	1-Octanol: ≤2ppm	0
Assay(anhydrous basis)	89.5%~102.0%	97.8%

Remarks: Research and Laboratory use only, Not to be used on Human, Animal, Food and Drug.

Shipment does not contain wood as packing material.

Conclusion: The results conform to EP7.

Analyst:	Checker:	QA.Manager: TY STAMP

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